

R E M A R K S

Claims 33, 35-37, and 47-50 are pending in this application.

Claims 33, 36, 37, and 47 have been amended as explained below.

Claims 1- 32, 34, 38-46, and 51-53 have been cancelled.

Claim 33 has been amended and it is respectfully requested that the objection to this claim be withdrawn.

The Examiner states on page 3 of the action that Claims 36-38 and 47 are rejected under 35 USC 112, second paragraph. This is respectfully traversed.

It is applicant's position that derivative is not indefinite especially in the context in which it is used in claim 36 wherein the derivative is a derivative of amoxicillin, ampicillin, cloxacillin, and clavulanic acid and is an active ingredient. However, to expedite prosecution, the phrase "derivative" has been deleted from claim 36.

Claim 37 has been amended to recite that the composition comprises a polymer in addition to the polymers required in claim 33.

Claim 47 was amended to reflect that the weight ratio of methacrylic acid polymer to polycarbophil is 10:1 to 1:10.

Therefore, it is respectfully requested that the rejection be withdrawn.

The Examiner states that claims 33, 35, 37-38 and 47 are rejected as being obvious over US Patent 5,614,222. This is respectfully traversed.

The Examiner states specifically that the '222 patent does not disclose a specific combination of bioadhesive polycarbophil polymer and Eudragit L-100. The Examiner bases his obviousness rejection essentially on the fact that both compounds are mentioned in the reference. The Examiner has not met the initial burden to "articulate reasoning with rationale underpinning to support the legal conclusion of obviousness". The Examiner has not established that (a) there is a motivation (or reason) for combining or modifying a reference or (b) that there is predictability or a reasonable expectation of success.

There is no teaching or suggestion in the '222 patent of a composition comprising at least one active ingredient and a polymer system comprising at least two polymers wherein at least one polymer is an acid insoluble methacrylic acid polymer and the other is a bioadhesive polycarbophil polymer as claimed in claim 33. The '222 patent discloses many different compounds, see for example col. 4, line 60-col.5, line 8; col. 5, lines 15-16 and col. 5, lines 33-52. There is no suggestion in this reference of the use of the two polymers as claimed in claim 33 and as such, the claims are patentable in view of this reference.

The Examiner's pointing to these two polymers is based on impermissible hindsight and as such, the claims are not obvious over the reference.

According to MPEP 2141 when applying 35 USC 103, the following tenets of patent law must be adhered to:

(A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention and (D) reasonable expectation of success is the standard with which obviousness is determined.

A reference must be considered for what it would teach someone skilled in the art at the time the invention was made and not be applied based on hindsight. See Panduit Corp. v. Dennison Manufacturing Co. 227 USPQ 337, 343 (Fed. Cir. 1985):

It is impermissible to first ascertain factually what applicants did and then view the

prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct appellants= invention from such prior art.

In making its obviousness determination, a court must view the prior art without reading into that art the patent's teachings. *Vandenberg v. Dairy Equipment*, 224 U.S.P.Q. 195 (Fed. Cir. 1987) citing *In re Sponnoble*, 160 U.S.P.Q. 237 (CCPA 1969). In *Uniroyal v. Rudkin-Wiley*, 50 U.S.P.Q.2d 1434, 1438 (Fed. Cir. 1988) the CAFC stated:

The obviousness standard, while easy to expound, is sometimes difficult to apply. It requires the decision maker to return to the time the invention was made. The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time...That which may be clear and thus obvious to a court, with the invention fully diagramed and aided by experts in the field, may have been a breakthrough of substantial dimension when first unveiled [citations omitted]. In this case we are convinced that the district court misapplied the obviousness standard. It has impermissibly used hindsight to reconstruct the claimed invention from prior art with the invention before it and aided by Uniroyal's expert, rather than viewing the invention from the position of a person of ordinary skill at the time it was made. When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.

Therefore, it is respectfully requested that this rejection be withdrawn.

The Examiner rejects claims 33, 35-38 and 47 under 35 USC 103(a) as being unpatentable over the '222 patent discussed above and US Patent 6979735. This is respectfully traversed.

Based on the Examiner's statement that "222 fails to disclose adding a second active ingredient listed in instant claim 36", it would seem that this rejection is incorrect and should be withdrawn. The mere fact that the reference mentions clavulanic does not make claim 36

obvious over this reference and the '222 patent because claim 36 includes a number of active ingredients.

Furthermore, as explained above, the claims are not obvious over the '222 patent.

Therefore, it is respectfully requested that this rejection be withdrawn.

Applicants submit that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,



JANET L. CORD
LADAS & PARRY LLP
1040 AVENUE OF AMERICAS
NEW YORK, NEW YORK 10018
REG.NO.33,778(212)708-1935